

Remarks

In response to the Examiner's Office Communication mailed on October 26, 2005, the Applicant has corrected the amendments to the claims filed on September 1, 2005 to indicate the status of claims 17-25. Following are responses to the Examiner's Office Action mailed on March 1, 2005.

In response to the Examiner's objections to claims 9 and 29 and the numbering of claims 25-33 (now 26-34), the Applicant has amended these claims to correct the spelling in claim 9 and to renumber claims 25-33 to 26-34, and respectfully notes that claim 29 (now 30) does further limit claim 28 (now 29) as originally written because claim 29 (now 30) recites a ratio of 1:1 while claim 28 (now 29) recites a ratio of 10:1.

In response to the Examiner's rejection of claims 9 and 31-34 under Section 112, second paragraph, the Applicant has amended claim 9 to clarify the meaning of "introducing" by replacing the word with "administering".

The Examiner has rejected claims 1-8 and 16-34 under 35 U.S.C. §103(a) as being unpatentable over Seow et al., Miller, Goodman and Gilman and Cousins. With regard to the independent claims, the Examiner states that Seow et al. teach administration of 2% lidocaine and 0.5% bupivacaine in a mixture in ratios of 3:1 to 1:3. In response the applicant respectfully traverses the Examiner's rejections.

To establish that a patent claim is obvious and invalid under 35 U.S.C. §103, the challenger is required to show by clear and convincing evidence that the differences between the subject matter of the patents-in-suit and the purported prior art are such that the subject matter of the claimed invention, as a whole, would have been obvious to someone skilled in the art at the

time of the invention. McGinley v. Franklin Sports, Inc., 60 U.S.P.Q.2d 1001, 1007 (Fed. Cir. 2001) and Ruiz v. A.B. Chance Co., 57 U.S.P.Q.2d 1161 (Fed. Cir. 2000), both citing, 35 U.S.C. §103(a). “Each fact forming the factual foundation upon which the court bases its ultimate conclusion regarding the obviousness of the claimed subject matter as a whole must be established by clear and convincing evidence.” Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., et al., 227 U.S.P.Q. 657, 663 (Fed. Cir. 1985)(citations omitted).

Although obviousness is ultimately a question of law, it is predicated on four underlying issues of fact, namely, (1) the scope and content of the prior art, (2) the differences between the claims and the prior art, (3) the level of ordinary skill in the art, (4) and secondary considerations of nonobviousness including commercial success, long felt but unresolved need, failure of others, copying, and unexpected results. Ruiz v. A.B. Chance, supra, citing, Graham v. John Deer Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) and Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 877, 27 U.S.P.Q.2d 1123, 1228 (Fed. Cir. 1993); and McGinley, supra, citing, Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966) and Kegel Co., Inc. v. AMF Bowling, Inc., 127 F.3d 1420, 1430, 44 U.S.P.Q.2d 1123, 1130 (Fed. Cir. 1997). These are the so called Graham factors.

With respect to secondary considerations, “[t]he so-called ‘secondary considerations’ provide evidence of how the patented device is viewed by the interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace.” Arkie Lures Inc. v. Gene Larew Tackle Inc., 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997); Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 7 U.S.P.Q.2d 1222, 1225 (Fed. Cir. 1988).

The test of obviousness is not whether an improvement, or part of a claimed invention, is obvious, but whether the claimed invention, when viewed as a whole, would have been obvious to someone skilled in the art. Carl Schenck A.G. v. Nortron Corp., 713 F.2d 782, 785 (Fed. Cir.

1983). Failure to consider the claimed invention as a whole is an error of law. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1548 (Fed. Cir. 1983). The question is not whether the individual elements existed in the prior art, but whether their combination would have been obvious. Id at 1543

The Graham test is especially important, and the danger of entering into the “forbidden zone of hindsight” increases, in cases in which “the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome.” Ruiz v. A.B. Chance, 57 U.S.P.Q.2d at 1166, quoting, In re Dembiczak, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999); Monarch Knitting Machinery Corp. v. sulzer Morat GmbH, 45 U.S.P.Q.2d 1977, 1981 (Fed. Cir. 1998)(court must not presume solution, defining the problem in terms of its solution reveals improper hindsight).

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." M.P.E.P. §2141.02, *citing*, Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 U.S.P.Q. 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983).

Secondary considerations of nonobviousness include commercial success, long felt but unresolved need, failure of others, copying, and unexpected results. Ruiz v. A.B. Chance, *citing*, Graham v. John Deer Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) and Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 877, 27 U.S.P.Q.2d 1123, 1228 (Fed. Cir. 1993).

[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art. Ruiz v. A.B. Chance Co., 57 U.S.P.Q.2d 1161, 1169 (Fed. Cir. 2000), quoting,

Stratoflex, 713 F.2d at 1538, 218 U.S.P.Q. at 879) Such evidence ‘may be sufficient to overcome a prima facie case of obviousness.’ Ruiz v. A.B. Chance Co., 57 U.S.P.Q.2d at 1169, quoting, In re Beattie, 974 F.2d 1309, 1313, 24 U.S.P.Q.2d 1040, 1043 (Fed. Cir. 1992).

As in Litton Systems Inc. v. Honeywell, Inc., 39 U.S.P.Q.2d 1321, 1327 (Fed. Cir. 1996), here there is substantial evidence of secondary considerations of nonobviousness including, that the primary references teach away from the invention.

As the Examiner noted, Seow et al. do not teach the claimed percentage of 1% lidocaine and 0.25% bupivacaine, but that Miller discloses that the usual concentration of lidocaine is 1-2% and the usual concentration of bupivacaine is 0.25% to 0.75%. However, Miller does not suggest combining the two anesthetics and Miller’s stated percentages are based on usage a single anesthetic, not a combination. In fact, Seow teaches away from the combination.

“A prior art reference may be considered to teach away from an invention when a person of ordinary skill, upon reading a reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 U.S.P.Q.2d 1977, 1984 (Fed. Cir. 1998). References that teach away from the modifying the prior art cannot create a prima facie case of obviousness. McGinley v. Franklin Sports, Inc., 60 U.S.P.Q.2d 1001, 1009 (Fed. Cir. 2001), citing, In re Gurley, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1131, 1132 (Fed. Cir. 1994).

Seow et al. teach away because they conclude that one of the important findings of their study was that the mixture “resulted in no substantial advantage over either agent alone.” The other important finding stated by Seow et al. was that the maximum blood concentrations

associated with the mixtures were the same as if the components had been injected individually.

Second, further evidence that the claimed invention is not obvious in view of the references comes from the lack of any other prior art commercialized embodiment. Despite the existence of older references cited, no one in the pharmaceutical industry has ever offered the claimed combination, and, it is only after the subject patent had issued, that a pharmaceutical company has begun copying the patented invention. Attached are two lists from the Orange Book, one is a list of drugs that include lidocaine and the other is a list of drugs that include bupivacaine. As can be seen by the lists, there is only one drug on both lists that is a combination of lidocaine and bupivacaine with a listed name of Duocaine. The application, designated as a “new combination” has yet to be granted a therapeutic equivalent designation as described in the third attachment. As the fourth attachment shows, Duocaine is based on a New Drug Application that was filed in 2003 by a company called Amphastar long after the subject patent issued.

Since no one in the highly competitive pharmaceutical industry has ever made or marketed the claimed combination, this is strong evidence that the combination is not obvious. Arkie Lures Inc. v. Gene Larew Tackle Inc., 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997)(“the years of use of [the prior art], without combining their properties, weighs on the side of unobviousness of the combination.”). When the prior art in question has been widely available for many years to persons skilled in the art without any suggestion to modify or combine, such widely available prior art is itself evidence of nonobviousness. Ruiz v. A.B. Chance, 57 U.S.P.Q.2d at 1168, quoting, PanduitCorp. v. Dennison Mfg. Co., 810 F.2d 1561, 1577, 1 U.S.P.Q.2d 1593, 1605 (Fed. Cir. 1987)(“[T]hat the elements noted by the court lay about in the

prior art available for years to all skilled workers, without, as the court found, suggesting anything like the claimed inventions, is itself evidence of nonobviousness.”).

The Examiner has rejected claims 9-15 under 35 U.S.C. §103(a) as being unpatentable over Seow et al., Miller, Goodman and Gilman and Cousins as applied above and further in view of Ko et al. The Examiner states that Ko et al. teach a method for reducing perioperative pain by injecting a preemptive analgesic solution before incision. In response, the Applicant respectfully traverses the rejection. For all the reasons set forth above, claims 9-15 are not obvious in view of this second combination in addition to the fact that Ko et al. also do not utilize the claimed percentages, as the Examiner noted.

As a general matter, the application of the numerous and various references and Official Notices to the Applicant's claimed invention is impermissible hindsight. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 10044, 1051-52, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988)(it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching or motivation in the prior art to do so); *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998)(“rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.”). The Court of Appeals for the Federal Circuit in *Pentec, Inc. v Graphic Controls Corp.*, 227 U.S.P.Q. 766 (Fed. Cir. 1985), stated that “prior art may not be gathered with the claimed invention in mind”. Similarly, in *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992), the Court noted:

Patent examination is necessarily conducted by hindsight, with complete knowledge of the applicant's invention, and the Courts have recognized the subjective aspects of determining whether an inventor would reasonably be

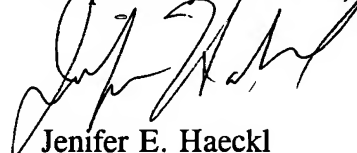
motivated to go to the field in which the examiner found the reference, in order to solve the problem confronting the inventor . . . It is necessary to consider 'the reality of the circumstances', . . . - in other words, common sense - in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness. 24 U.S.P.Q.2d at 1446.

The suggestion, teaching or reason must come from the prior art itself, it cannot be based on hindsight in view of the claims. McGinley v. Franklin Sports, Inc., 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001), citing, In re Dembiczak, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1769 (Fed. Cir. 1999)“(guarding against falling victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher).” Whether such a motivation existed is a question of fact. Id. Evidence of any purported motivation must be “clear and particular.”” Ruiz v. A.B. Chance, 57 U.S.P.Q.2d at 1168, quoting, In re Dembiczak, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617 (Fed. Cir. 1999).

Each of the Examiner's objections and rejections has been addressed. As such the Applicant respectfully believes the claims are in condition for allowance.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned in Worcester, Massachusetts at (508) 791-8500.

Respectfully submitted,



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